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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,118	09/24/2003	Salim Yusuf	16554-002002 / H310864USC	2545
26161	7590	10/23/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,118

Applicant(s)

YUSUF ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, claim 11 in the reply filed on 31 July 2006 is acknowledged.

Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) and 35 USC 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/307,883 and PCT/CA03/00422, fails to provide adequate support or enablement in the manner

provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The competitive assay system of claim 11 requires a first strip having an unlabeled antibody specific for thromboxane B2 and second strip impregnated with a standard concentration of labeled thromboxane B2; however, these strips are NOT disclosed in the provisional application 60/307,883 nor PCT/CA03/00422.

'883 and '422 both disclose an embodiment where the first strip (1) has a fixed concentration labeled antibody specific for thromboxane B2 and the second strip (7) is made of a material designed to absorb a fixed volume of liquid sample. The first strip may also have protein A or G to facilitate the attachment of the labeled antibody to the strip. No where in these two documents can support be found for the immunoassay system of claim 11.

Therefore, this application is only entitled to the instant filing date of 24 September 2003.

In the event that applicant believes support may be found, Applicant is requested to point to the page and line number where such support is located.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guire et al (US 4,826,759) in view of Reinke et al (IDS - AT).

The instant claim is drawn to an immunoassay system comprising a first strip having antibody specific for thromboxane B2, and a second strip impregnated with a standard concentration of labeled thromboxane B2. The recitation of intended use is not given patentable weight.

Guire discloses an apparatus in the form of a strip comprising a support means provided with a groove intermediate its ends forming a crease line upon which the strip can be folded upon itself. The strip comprising bibulous elements made of filter paper. Guire teaches that the device is suitable for a variety of analytes and make use of ligand-receptor pairs and labeled pair member as detection. See column 1, line 52

through column 2, line 30. Guire specifically teaches an embodiment where enzyme-labeled analyte is impregnated in one bibulous element and anti-analyte antibody is loaded in another bibulous element. In use, sample is added to the first element and the device is folded to bring the two elements into contact. The contacting elements are pinched together momentarily to transfer liquid from one element to the other element, following which the apparatus is opened and the elements are observed for the development of color. See column 7, lines 58 through column 8, line 57 and claim 5.

Guire differs from the instant invention in failing to teach that the apparatus contains antibody specific for thromboxane B2 and standard concentration of labeled-thromboxane B2.

Reinke, however, discloses the importance of detecting thromboxane B2 and teaches assays for their detection. Reinke discloses thromboxane B2-BSA conjugates, monoclonal antibodies specific to thromboxane B2 and three different types of enzymes detection system.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Guire to detect thromboxane B2 using the reagents taught by Reinke because Guire teaches that their device is suitable for a variety of analytes with the choice of appropriate reagents. A skilled artisan would have had a reasonable expectation of success in using the device taught by Guire to detect thromboxane B2 because Reinke teaches that the measurement of thromboxane is important because an increase in biosynthesis of

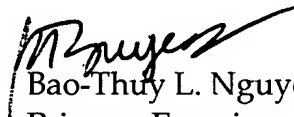
thromboxane is observed in patients with coronary diseases as well as a hosts of other problems, and Guire teaches that their device is unique in that it can be readily and easily used or performed by minimally trained personnel.

Conclusion

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 10.11.06